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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 10/071,505 | 02/08/2002 | Ingrid Henriksen | NIDN-10439 | 8899 |
| 36335 | 7590 | 06/17/2004 | | |
| AMERSHAM HEALTH IP DEPARTMENT 101 CARNEGIE CENTER PRINCETON, NJ 08540-6231 | | | EXAMINER SHARAREH, SHAHNAM J | |
| | | | ART UNIT 1617 | PAPER NUMBER |

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 10/071,505 | Applicant(s) HENRIKSEN ET AL. | |
| | Examiner Shahnam Sharareh | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed on March 25, 2004 has been entered. Claims 1-17 are pending. Claims 13-17 are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 8-9 are also withdrawn from further consideration as being drawn to the nonelected species. Election was made **without** traverse in Paper No. 9.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-7, 10-12 read on the elected species.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Vaughn US Patent 5,242,392.

Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that the flush chamber in the apparatus of Vaught is positioned lower than the IV bag so that the content of the IV bag empty before the contents of the flush chamber empty. (see page 7 of the Arguments).

In response Examiner states that Applicant's conclusion is not commensurate with the scope of the pending claims. First, the instant claim is not

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limited to position of a flushing chamber. Therefore, such reasoning is moot on its face. Second, the fact that such chamber is positioned before the IV bag is irrelevant to the way such line is used, because such chamber can be use to clear the line before administration of any type of drug to avoid incompatibility issues with subsequent drugs that are administered intravenously.

Vaughn specifically elaborates on the method of using such apparatus whereby a flush solution such as normal saline is delivered from item 52 (the primary flush solution vessel) into the tubing 24. (see col 5, line31-33; col 7, lines 50-col 8, lines 20). Item 34 (the medicine vessel) contains about 50-150 cc of a medicine in solution or suspension, such as an antibiotic formulation in normal saline. (col 6, lines 15-29). Vaughn finally teaches that both the medicine in the form of a suspension from item 34 and the flushing solution from item 52 are mixed in the tubing 24 prior to being administered to the patient. (col 7, line 19-line 35).

With respect to the newly added limitation “ to enhance product homogeneity,” Examiner replies that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136

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USPQ 458, 459 (CCPA 1963). Here, the method steps are not different from those disclosed by Vaughn; thus, such limitation is anticipated.

Claim Rejections - 35 USC § 103

3. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn in view of Remington, *The Science and Practice of Pharmacy* 19th edition, pages 1552-1554, (Remington).

4. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, it is the combined teachings of the references that render the instant claims obvious.

Applicant first argues that Remington does not describe gravity to provide for administration of IV drugs (see page 8 of the arguments). In response Examiner replies that the claimed invention does not require such limitation, therefore, such line of argument is moot. Second, Vaughn and the general knowledge in the art of administering IV admixtures provide such teaching. In fact, contrary to Applicants statements Remington teaches piggyback bags that essentially achieve the same function as the delivery vessel. (See 4th para at page 1552, and figure 6, 7, pages 1552-1554).

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Thus, as previously stated, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Vaughn's method by using a syringe instead of a biggyback bag, because as taught by Remington, the ordinary skill in the art would have had a reasonable expectation of success in effectively delivering a drug of choice when substituting a syringe in place of a biggyback bag to administer a drug of choice into the flushing solution.

5. Claims 1-7, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vaughn in view of Remington as applied to claims 1-3 above, and further in view of Unger WO 97/48337.

6. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive. Applicant argues that Unger teaches flushing after injection of his drug composition. (see Arguments at page 8).

Again as reasoned above, it is the combined teachings of the references that render the instant claims obvious.

Accordingly, administration of flushing solution prior to the drug composition is described by the combined teaching of Vaughn and Remington. In fact such step is routinely practiced in clinical setting a means to clear lines to avoid intratubal drug interaction. Unger is merely used to show that gaseous dispersions are also administered intravenously into a primary flushing line such as those describe by Vaughn.

Therefore, one of ordinary skill in the art would have been motivated to do such modifications because as suggested by Vaughn, employing his method would allow the entire contrast agent to be administered. Further, as suggested

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by Unger, using a flushing solution with a contrast agent reduces diagnostic artifacts. Therefore, claims 1-7, 10-12 are prima facie obvious in view of the cited references. Accordingly, the rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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